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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,583	01/14/2002	Atef Boulos	BP-8935B CIP	7434

23914 7590 03/12/2003

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: ~~03/12/2003~~
Restart 10-17-03

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,583	BOULOS ET AL.	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tritsch et al. (US Pat. 6,030,645) in view of Boyle et al. (US Pat. 5,925,381), EP 0 595 005 and Schmidt et al. (US pat. 4,486,435).

Tritsch et al. teach the preparation of flowable dry particles having an oleophilic active ingredient, such as vitamin E dispersed in a carrier material, and a coating layer comprising mixtures of calcium, microcrystalline cellulose, magnesium silicate and silicon dioxide, and the composition can further include mixtures of vitamins and/or minerals (Columns 2-4). It is taught that the flowable dry particles are well suited for the manufacture of tablets as they having outstanding flow and compressibility behaviour (Column 3, lines 47-51).

Boyle et al. teach the preparation of encapsulated oleophilic substances, such as vitamin E, in the form of powders which are suitable for tableting wherein the composition contains the encapsulated vitamin E, calcium silicate, microcrystalline cellulose and Cab-O-Sil (See entire document, especially Column 10, lines 60-68, Column 11, lines 1-33). It is taught that the preparation allows for production of high potency vitamins in a free flowing powder form (Column 1, lines 33-41).

EP 0 595 005 teaches a composition and method in the form of tablets or coated tablets effective in lowering homocysteine levels for the treatment of cardiovascular diseases containing a mixture of vitamins and minerals, including Vitamin E, for example, tocopherol acetate, and selenium (Pg. 2, lines 1-20, Pg. 5, lines 55-58, Pg. 6, lines 54-59, Pg. 7, lines 1-21). A tablet formulation containing microcrystalline cellulose is taught (Pg. 15, lines 10-56, Pg. 16, lines 1-14).

Schmidt et al. teach a hydrophobic silica formed from precipitated silica which is used in the formulation of tablets for vitamin mixtures, including vitamin E, which are prepared by spray drying droplets of vitamins (Column 1, lines 35-40, 63-67, Column 2, lines 20-34, Column 3, lines 20-23). It is taught that the hydrophobic silica has improved flow and reduces sticking of the powder (Column 1, lines 68, Column 2, lines 1, 2). It is taught that the composition can contain adjuvents which are conventional in vitamin-containing powders, for example, lubricant compounds, for example talc, binders and fillers (Column 2, lines 13-15).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a composition or method of providing a cardiovascular benefit containing in combination encapsulated vitamin E, precipitated silica, calcium silicate, microcrystalline cellulose, and, optionally, talc. However, the prior art amply suggests the same as it is known in the art to formulate mixtures of vitamin, including Vitamin E, and minerals in the form of tablets or coated tablets for the reduction of homocysteine levels. Further, it is known in the art to prepare tablets by spray drying mixtures of vitamins using conventional lubricants and fillers, such as calcium silicate, microcrystalline cellulose, talc and precipitated silica. As such, it would have been well within the skill of one of ordinary skill in the art to formulated a composition

which would lower homocysteine levels containing encapsulated vitamin E, precipitated silica, calcium silicate, microcrystalline cellulose and talc and arrive at the various ratios and concentrations through optimization of the prior art values depending of effectiveness of the active ingredients and flowability and compressability of the powders in the tableting process. Further, one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the lubricant and fillers would facilitate processing of the tablet and the tablet composition would be effective in lowering homocysteine levels and provide a cardiovascular benefit.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC
March 6, 2003

JOHN PAK
PRIMARY EXAMINER
GROUP 1600